IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appln. No.	:	10/007,812
Applicant	:	ROBERT S. SUPINSKI
Filed	:	November 8, 2001
Title	:	PATELLA REPLACEMENT APPARATUS
Group Art Unit	:	3733
Examiner	:	David C. Comstock
Docket No.	:	011072
Confirmation No.	:	6892

BRIEF ON APPEAL

Real Party in Interest

The real party in interest is the applicant, Dr. Robert S. Supinski.

Related Appeals and Interferences

There are no related appeals or interferences.

Status of Claims

Claims 1 through 21 are pending in the application. The status of the claims is that claims 1 through 21 have been rejected. Applicant is appealing the rejection of claims 1 through 21.

Status of Amendments

No amendments were filed after the Final Office Action dated June 12, 2008 from which this appeal is taken.

Summary of Claimed Subject Matter

The claims on appeal are directed to a device that is used to replace a damaged patella in a patient. The patella is a bone in the knee that is sometimes called the knee cap. Should the

patella be damaged, as sometimes occurs when a patient is in an automobile accident, a surgeon can remove all or a portion of that bone and implant an artificial replacement. There are many examples of replacement devices available to surgeons. Indeed, the prior art references relied upon by the Examiner all disclose devices that can be implanted to replace a portion of a natural patella.

Patella replacement devices must be able to fix biologically to remnant bone or soft tissue such as muscle or tendon. See Applicant's specification at page 2, lines 6-7. Applicant has disclosed and claimed a patella replacement device having two members coupled together. The claims specify the shape and composition of these two members and that the device must have a shape conforming to a natural patella. This is an important distinction because the prior art devices disclosed in the references cited by the Examiner do not replace the patella but are implants that are attached to a portion of the natural patella. They have a projection that is fitted into a hole or slot cut into the natural patella.

Claim 1 is an independent claim directed to a patella replacement device for use in repairing or replacing the destroyed natural patella of a patient. The claimed device has a first member and a second member illustrated as parts 11 and 12 in Figures 1 through 4, or parts 21 and 22 shown in Figure 5 or parts 31 and 32 shown in Figures 8 and 9. The first member is fabricated from a biocompatible porous metal material and has a rounded fixation surface for implantation in the patella region of a patient. The porous metal allows biological fixation to the patella region of the patient. The first member also has a relatively flat surface opposite the rounded surface and there is at least one aperture in that surface. There is a second member fabricated from a biocompatible material that has a top rounded surface and an opposing surface having an extending projection that fits into the aperture in the first member to couple the two

parts together. The second member allows articulation against the femoral area of the patient. Specification at page 4, line 20 through page 6, line 2, and at page 7, lines 1-20. The patella replacement device must have a shape conforming to a natural patella of a typical patient. See the specification at page 6, lines 19-20.

Claim 2 depends from claim 1 and requires an annular ring extending from the first member. This ring has a plurality of apertures about its periphery. This ring 24 and apertures 25 can be seen in Figures 5, 6 and 7 and is described at page 7, lines 3-20 of the application.

Claim 3 depends from claim 2 and requires that annular ring be fabricated from a biocompatible material. Support for this claim can be found in the application at page 7, line 5.

Claim 4 also depends from claim 3 and requires that first member be titanium. Claim 5 depends from claim 1 and requires that the second member be fabricated from polyethylene. Claim 6 depends from claim 1 and requires that the second member be fabricated from titanium or cobalt chrome. Support for these claims can be found in the application at page 7, line 5.

Claim 7 depends from claim 1 and requires at least one annular collar 13 and 14 shown in Figures 1 through 4 attached to the first member or the second member or both members. This is described at page 5 of the application at lines 9-11.

Claim 8 is an independent claim for a patella replacement device similar to that claimed in claim 1. However, this device must have a peripheral gap formed between the first member and the second member when they are assembled together. This gap enables the accommodation of soft tissue. This embodiment is shown in Figures 2 and 5 and is described at page 8, lines 4-9.

Claim 9 depends from claim 8 and requires an annular ring having apertures about a periphery of the ring. The apertures 25 can be seen in the ring 24 in Figure 7 and are described at page 7, lines 17-18.

Claim 10 depends from claim 8 and requires that annular ring be fabricated from a biocompatible material. Support for this claim can be found in the application at page 7, line 5.

Claim 11 also depends from claim 8 and requires that first member be titanium. Claim 12 depends from claim 8 and requires that the second member be fabricated from polyethylene. Claim 13 depends from claim 8 and requires that the second member be fabricated from titanium or cobalt chrome. Support for these claims can be found in the application at page 7, lines 5-8.

Claim 14 depends from claim 8 and requires the first member to have three apertures and the second member to have three projections adapted to coact with the three apertures. The apertures 18 are shown in Figure 3.

Claim 15 is an independent claim directed to a patella replacement device that is made from two members 21, 22 and an annular ring 24 secured around the first member. These features are shown in Figures 5 and 7. The first member is fabricated from a porous metal material, has a rounded fixation surface for implantation in the patella region of a patient and has a flat surface containing at least one aperture opposite the rounded surface. The second member is also fabricated from a biocompatible, has a top rounded surface and has an opposing surface from which a projection extends and that fits into the aperture in the first member to couple the two parts together in a way that creates a peripheral gap between the two members. This is described at page 8, lines 3-8 of the specification.

Claim 16 depends from claim 15 and requires that the ring be secured to the first member by an interference fit as described at page 7, lines 14-15 of the application. Claim 17 depends from claim 15 and requires that the second member be fabricated from polyethylene as disclosed at page 7, line 8 of the application.

Claim 18 also depends from claim 15 and requires that the ring be fabricated from titanium as described at page 7, line 4 of the application.

Claim 19 depends from claim 15 and requires the first member to have three apertures on the flat surface. Claim 20 depends from claim 19 and requires the second member to have three projections adapted to coact with the three apertures. The apertures 18 can be seen in Figure 3 and the posts 17 are illustrated in Figures 2 and 4.

Claim 21 depends from claim 15 and says that the porous metal must accommodate bone cement placed in at least one aperture. This is disclosed at page 5, line 18 of the application.

Claim 22 is an independent claim directed to a patella replacement device for use in repairing or replacing the destroyed natural patella. Like claim 1, claim 22 says that the device has a first member and a second member illustrated as parts 11 and 12 in Figures 1 through 4, or parts 21 and 22 shown in Figure 5 or parts 31 and 32 shown in Figures 8 and 9. The first member is fabricated from a biocompatible porous metal material and has a rounded fixation surface for implantation in the patella region of a patient. The first member has a relatively flat surface opposite the rounded surface and there is at least one aperture in that surface. There is a second member fabricated from a biocompatible material. The second member has a top rounded surface and an opposing surface having a projection that fits into the aperture in the first member to couple the two parts together. The patella replacement device must have a shape conforming to a natural patella of a typical patient. See the specification at page 6, lines 19-20. Claim 22 further requires a porous coating containing a bone growth material be on at least a portion of either the first member or the second member. This is described in the application at page 9, lines 4-22.

Claim 23 depends from claim 22 and says that the bone growth material is selected from the group consisting of hydroxyapatite, human bone particles, bovine bone particles, ground coral and calcium sulfate. Support for this claim can be found at page 10, lines 1-4 of the specification.

Claim 24 depends from claim 22 and says one or both of the first member and the second member are fabricated from biocompatible metals, biocompatible plastics or biocompatible ceramics. This is described in the application at page 9, lines 7-10.

Claim 25 says that the first member is fabricated from a metal and said second member is fabricated from a plastic and depends from claim 22. Claim 26 depends from claim 25 and says that the plastic is polyethylene and the metal is titanium or cobalt chrome. This is described in the application at page 9, lines 9-12 and at page 5, lines 3-5.

None of the claims contain means function clauses.

Grounds of Rejection to be Reviewed

1. Rejection of claims 1, 5-8 and 12-14 as being unpatentable under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,522,901 to Thomas.

2. Rejection of claims 1, 5-8 and 12-14 as being unpatentable under 35 U.S.C. 103(a) over Thomas.

3. Rejection of claims 2-4, 9-11 and 15-21 as being unpatentable under 35 U.S.C. 103(a) over Thomas in view of U.S. Patent No. 4,041,550 to Frazier.

4. Rejection of claims 22-26 as being unpatentable under 35 U.S.C. 103(a) over Thomas in view of U.S. Patent No. 5,609,640 to Johnson.

Argument

The Examiner has rejected all of the pending claims as either fully disclosed by United States Patent No. 5,522,901 to Thomas et al. or obvious from Thomas et al. in combination with United States Patent No. 4,041,550 to Frazier, or United States Patent No. 6,280,476 to Metzger et al., or United States Patent No. 5,609,640 to Johnson.

A. Rejection of claims 1, 5-8 and 12-14 as being unpatentable under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,522,901 to Thomas.

For a claim to be anticipated by a prior art reference, that reference must describe every element and limitation of the claim, either expressly or inherently, so as to place a person of ordinary skill in the art in possession of the invention. See Schering Corp. V Geneva Pharms., Inc. 339 F3d 1373, 1378, 67 USPQ2d 1664 (Fed. Cir. 2003).

1. The Thomas reference

The '901 Thomas patent discloses an implant for replacing a rear patella part. This implant is not suitable for replacing the entire natural patella of a patient. The abstract says that "the implant can be attached in the natural patella part." As clearly shown in Figure 1 of this patent, the implant has an attachment part 10 that fits into a cavity cut in the natural patella 1. The first paragraph in column 3 of the patent teaches that the "rear patella part is resected" (i.e. cut back) such that a spherical depression 16 is created in the front natural patella part. The implant has an attachment part 10 made from metal which is placed into the spherical depression. Column 3, lines 6-7. Such attachment can be made using bone cement, but not using sutures. This part has an open-cell or open pore surface structure." Column 3, lines 8-9. The attachment part fits into a prosthesis part 2 made from plastic or ceramic material. Column 3, lines 8-9.

The assembled structure of Thomas does not have a shape that conforms to a patella of a typical patient. Rather, there is a projection 16 that fits into a cavity cut in the natural patella that remains in the patient. A natural patella does not have any such projection. The assembled implant also does not have an annular ring that extends from the peripheral edge of the attachment surface of the attachment part. The structure 32 identified by the Examiner as a protruding annular ring fits into the prosthesis part 2. Consequently, this part 32 does not meet the requirements for the ring in amended claim 2. There is no gap between the attachment part and the prosthesis part. There are no coatings on the implant. There is no teaching or suggestion to use a bone growth material anywhere in the implant.

2. None of the claims as amended are anticipated by Thomas

The Examiner rejected claims 1, 5-8 and 12-14 as anticipated by Thomas. Claim 1 requires that the patella replacement device have a shape conforming to a natural patella. The device disclosed by Thomas does not have a shape conforming to a natural patella. Thomas's implant has a projection 16 on one side that is inserted into a cavity cut in a natural patella 1.

Claims 5-7 depend from claim 1. Claim 8 is similar to claim 1 but requires a peripheral gap between the first and second member. Claims 12-14 depend from claim 8. Thomas does not teach or suggest a peripheral gap. Accordingly, none of these claims are anticipated by Thomas. Structure 16 in Thomas does not extend from the peripheral edge of the attachment part, but rather protrudes from the surface and mates with the prosthesis part.

Accordingly, the Examiner's rejection of claims 1, 5-8 and 12-14 as unpatentable under section 102(a) should be reversed.

B. Rejection of claims 1, 5-8 and 12-14 as being unpatentable under 35 U.S.C. 103(a) over Thomas.

To establish a prima facie case of obviousness, three basic criteria must be met. "First, there must be some suggestion or motivation, in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings." MPEP § 2142. "Second, there must be a reasonable expectation of success." *Id.* "Finally, the prior art reference (or references when combined) **must teach or suggest all the claimed limitations.**" *Id.* (emphasis added). "The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure." *Id.*

To suggest or teach toward an invention, the "prior art must suggest the desirability of the claimed invention." MPEP § 2143.01. "**The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination.**" *Id.* (emphasis added).

Further, any proposed change or modification of prior art must not change the principle of operation disclosed by the reference. *Id.* For example, a proposed modification of a prior art invention must not render the modified device unsatisfactory for its intended purpose. *Id.*

Thomas does not teach or suggest that his implant be modified to assume the shape of a natural patella or to have a gap between the two main parts of his implant. Indeed, by teaching at col. 1 lines 50-53 of his patent that the implant must have a contact face shaped to fit into and abut a rounded surface cut into the natural patella. If one changed the shape of the Thomas implant to conform to the shape of a natural patella, that device could not be fit into and abut a cavity cut in a natural patella. Thomas is teaching away from the invention claimed by applicant.

C. Rejection of claims 2-4, 9-11 and 15-21 as being unpatentable under 35 U.S.C. 103(a) over Thomas in view of U.S. Patent No. 4,041,550 to Frazier.

United States Patent No. 4,041,550 to Frazier discloses two embodiments of an artificial patella having a rigid wafer-like member 11 having several small circular openings. The first embodiment shown in Figures 1 and 2 is used when the natural patella has been removed. The rigid wafer-like member is attached to the patella tendon by sutures that pass through selected openings. A patella prosthesis is attached to the wafer-like member by bone cement. Column 2, lines 26-29. The patella prosthesis 14 is attached by a snap fit to a femoral prosthesis 17 that is secured to the femur by bone cement and pegs. Column 2, lines 32-52. A second embodiment shown in Figure 5 is used when a portion of the natural patella is present. This embodiment has short "pegs 19a on its [the wafer-like part] outer side which are adapted to extend into complementary opening formed in the adjacent surface of the remaining natural patella 20a." col. 3, lines 23-25. The wafer-like member is secured to the remaining natural patella "partly by means of short pegs 19a which are held by bone cement " col. 3, lines 30-33. This second embodiment is similar to the implant disclosed by Thomas in that both implants have a projection that is inserted into a cavity cut in a natural patella. None of these components in Frazier's implant have a rounded fixation surface. The assembled structure cannot articulate against the femur or the femoral area of the patient. Articulation occurs at the snap fit connection. There is no annular ring or peripheral gap between the wafer-like member 11 and the patella prosthesis 14. There is also no teaching or suggestion of bone growth material on the artificial patella.

The Examiner has rejected claims 2-4, 9-11 and 15-21 as unpatentable over Thomas in view of Frazier. Claim 2 requires that the ring encircle the rounded fixation surface. At page 4 of the Final Office Action the Examiner asserts, "Frazier discloses a patellar implant and teaches

providing a plurality of apertures about a periphery of the device in order to allow sutures to pass therethrough and retain a damaged patella in place (see, e.g., Figs. 2 and 4, col. 1 lines 5-8 and col. 2, lines 15-21)." Only Figures 4 and 5 show the implant being attached to remaining natural patella. The patent teaches at column 3 that the implant is attached to the remaining bone "by means of short pegs 19a which are held by bone cement." col. 3, lines 30-33.

One skilled in the art reading Thomas in combination with Frazier would learn that one can attach an implant to remaining patella bone by forming a cavity in that remaining bone and providing a projection on the implant that fits into the cavity. One would also learn that one could use bone cement in that cavity. Thomas requires that there be at least some remaining bone for his implant. The second embodiment of Frazier also requires that there be some remaining patella to which the implant is attached by one or more projections. Thus, one skilled in the art reading Thomas and Frazier would be lead to an implant having one or more projections for insertion into one or more cavities cut in the remaining natural patella. To the extent that the combination of references teaches anything about implants for situations where no natural patella exists, that teaching is limited to the first embodiment of Frazier. Importantly, none of the implants taught by the combination of Thomas and Frazier have a shape conforming to a natural patella. Therefore, claim 1 and the claims that depend from claim 1 are patentable over this combination.

D. Rejection of claims 22-26 as being unpatentable under 35 U.S.C. 103(a) over Thomas in view of U.S. Patent No. 5,609,640 to Johnson.

The Examiner has rejected claims 22-26 as unpatentable over Thomas in view of Johnson. United States Patent No. 5,609,640 discloses a patella prosthesis having a mushroom shaped member with a head that is contoured to correspond to a human patella. The entire prosthesis, however, is not shaped to conform to a natural patella. Johnson teaches that

hydroxyapatite coating may be applied to the implant. Like Thomas and Frazier, the implant disclosed by Johnson has a projection 2 from one surface. Claim 22 requires that the implant have a shape conforming at a natural patella. The implant disclosed by Johnson has no such shape.

Taken together, none of the prior art references cited by the Examiner teach or suggest an implant for replacing a damaged patella in which the implant has a shape corresponding to a natural patella. Instead, the art teaches to have a flat surface which is sewn to the tendon or to provide one or more projections which are inserted into a corresponding cavity or cavities cut in the remaining natural patella. For these reasons the pending claims would not have been obvious to one skilled in the art who was familiar with the cited references.

CONCLUSION

For the foregoing reasons the claims on appeal are patentable over the cited references. Reversal of the rejections of the appealed claims is respectfully requested.

Respectfully submitted,

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Appendix

Claims on Appeal

1. A patella replacement device for use in repairing or replacing the destroyed natural patella of a patient, comprising:

a first member fabricated from a biocompatible porous metal material and having a rounded fixation surface for implantation in the patella region of a patient with the porous metal allowing biological fixation to the patella region of the patient, said first member having a relatively flat surface opposite said rounded surface and having at least one aperture therein; and

a second member fabricated from a biocompatible joint articulating material and having a top rounded surface and an opposing surface having an extending projection for coacting with said aperture to enable said first member to couple to said second member with said second member operative to allow articulation against the femoral area of said patient;

the patella replacement device having a shape conforming to a natural patella of a typical patient.

2. The patella replacement device according to claim 1 further comprising an annular ring having a central aperture for coupling to said flat surface of said first member and having a plurality of apertures about a periphery of said ring, the periphery encircling the rounded fixation surface and extending from a peripheral edge of said first member.

3. The patella replacement device according to claim 2 wherein said annular ring is fabricated from a biocompatible metal.

4. The patella replacement device according to claim 3 wherein said metal is titanium.

5. The patella replacement device according to claim 1 wherein said second member is fabricated from polyethylene.

6. The patella replacement device according to claim 1 wherein said second member is fabricated from titanium or cobalt chrome.

7. The patella replacement device according to claim 1 also comprising at least one annular collar attached to at least one of the first member and the second member.

8. A patella replacement device for use in repairing or replacing the destroyed natural patella of a patient, comprising:

a first member fabricated from a porous metal material and having a rounded fixation surface for implantation in the patella region of a patient with said porous metal allowing biological fixation to said patella region of said patient, said first member having a relatively flat surface opposite said rounded surface and having at least one aperture therein, and

a second member fabricated from a biocompatible material and having a top rounded surface and an opposing surface having an extending projection for coacting with said aperture in said first member and dimensional so that a peripheral gap is formed between said first and second member when said projection is inserted into said aperture, said gap enabling the accommodation of soft tissue.

9. The patella replacement device according to claim 8 further comprising:

an annular ring having a central aperture for coupling to said flat surface of said first member and having a plurality of apertures about a periphery of said ring, the periphery surrounding and extending from a peripheral edge of said first member.

10. The patella replacement device according to claim 9 wherein said annular ring is fabricated from a biocompatible metal.

11. The patella replacement device according to claim 10 wherein said metal is titanium.

12. The patella replacement device according to claim 8 wherein said second member is fabricated from polyethylene.

13. The patella replacement device according to claim 8 wherein said second member is fabricated from titanium or cobalt chrome.

14. The patella replacement device according to claim 8 wherein said relatively flat surface of said first member has three apertures, with said second member having three projections each adapted to coact with a respective associated one of said apertures.

15. A patella replacement device for use in repairing or replacing the destroyed natural patella comprising:

a first member fabricated from a porous metal material, said first member having a rounded fixation surface for implantation in the patella region of a patient, and a relatively flat surface opposite said rounded surface, said flat surface having at least one aperture therein;

an annular ring secured about said first member, said ring having a central aperture, an extending flange portion surrounding said first member and a plurality of apertures about a periphery thereof; and

a second member fabricated from a biocompatible material having a top round surface and an opposing surface having an extending projection for coacting with said aperture in said first member and dimensioned so that a peripheral gap is formed between said first and second members when said projection of said second member is inserted into said aperture of said first member.

16. The patella replacement device according to claim 15, wherein said annular ring is secured to said first member by an interference fit.

17. The patella replacement device according to claim 15 wherein said second member is fabricated from polyethylene.

18. The patella replacement device according to claim 15 wherein said annular ring is fabricated from titanium.

19. The patella replacement device according to claim 15 wherein said first member has three apertures on said flat surface.

20. The patella replacement device according to claim 19 wherein said second member has three projections each one operative to coact with an associated one of said three apertures of said first member.

21. The patella replacement device according to claim 15 wherein said porous metal material accommodates a bone cement placed in said at least one aperture.

22. A patella replacement device for use in repairing or replacing the destroyed natural patella of a patient comprising:

a first member fabricated from a biocompatible material and having a rounded fixation surface for implantation in the patella region of a patient, said first member having a relatively flat surface opposite said rounded surface and at least one aperture therein;

a second member fabricated from a biocompatible material and having a rounded surface and an opposing surface having an extending projection for coacting with said aperture to enable said first member to couple to said second member; and

a porous coating containing at least one bone growth material and applied to at least a portion of at least one of said first member and said second member;

the patella replacement device having a shape conforming to a natural patella of a typical patient.

23. The patella replacement device according to claim 22 wherein the at least one bone growth material is selected from the group consisting of hydroxyapatite, human bone particles, bovine bone particles, ground coral and calcium sulfate.

24. The patella replacement device according to claim 22 wherein at least one of said first member and said second member is fabricated from a material selected from the group consisting of biocompatible metals, biocompatible plastics and biocompatible ceramics

25. The patella replacement device according to claim 22 wherein said first member is fabricated from a metal and said second member is fabricated from a plastic.

26. The patella replacement device according to claim 25 wherein said plastic is polyethylene and said metal is titanium or cobalt chrome. .

Evidence Appendix

None.

Related Proceedings Appendix

None.